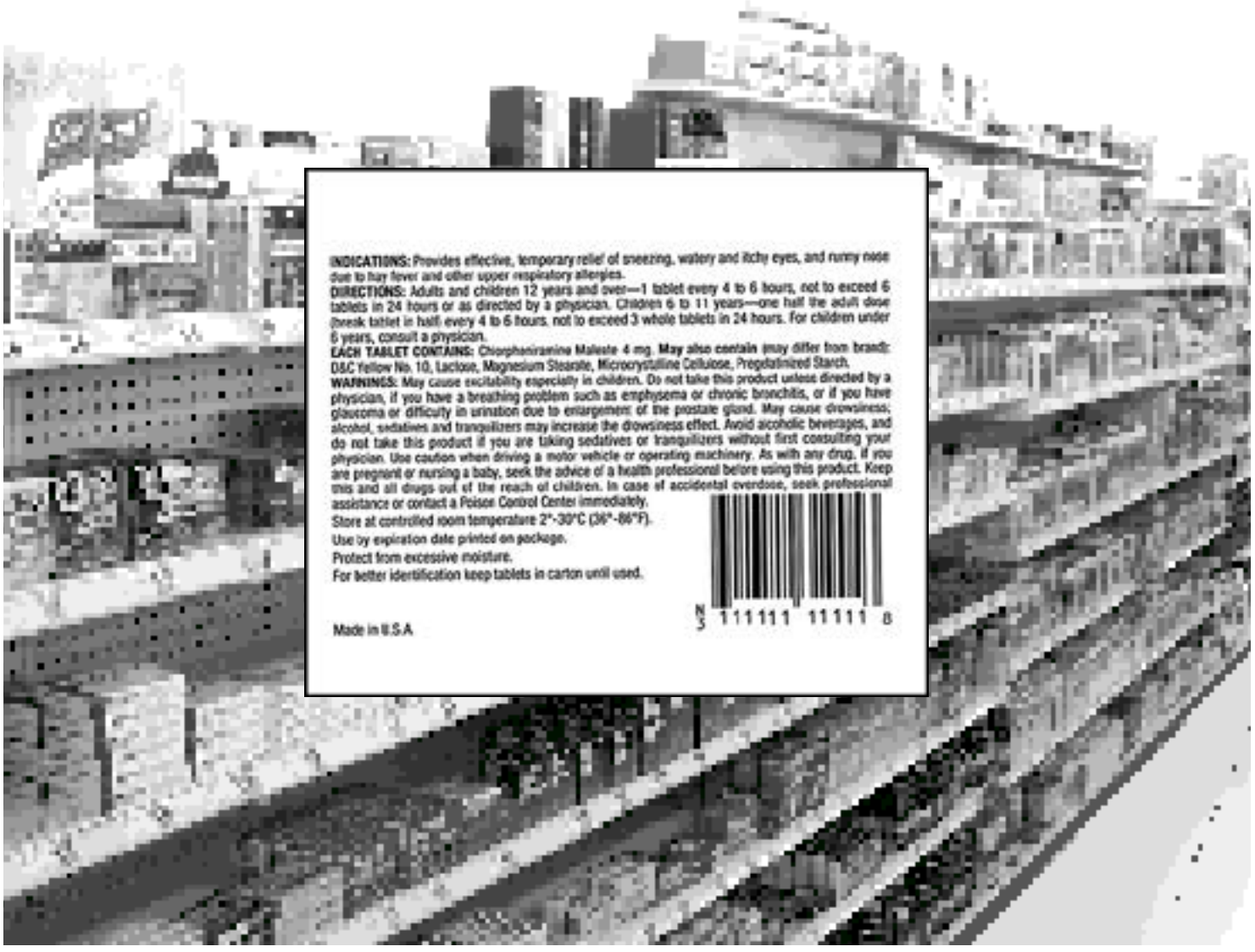
New Drug Label Spells It Out Simply



There's a simpler substitute for the word "assistance": help. For "discard": throw away. And for "aggravate": make worse.

Soon, consumers could see the plain-speaking terms in place of longer, harder-to-understand ones on everything from aspirin for aches and pains to zinc chloride for canker sores. A new Food and Drug Administration regulation allows these pairs of words and some others to be used interchangeably on the labels of nonprescription, or "over-the-counter," drugs.

In addition to permitting some word swaps, the new rule requires that all OTC drug labels contain certain information—such as ingredients, doses and warnings—in a standardized format.

The rule, published in the March 17, 1999, *Federal Register*, covers some 100,000 nonprescription products, including those like sunscreens that have both drug and cosmetic uses. The goal of the uniform label is to help consumers understand a nonprescription drug's benefits and risks and take the medicine correctly.

The new rule, said Vice President Al Gore when he announced it March 11, will "ensure that the labels on medicine we buy over the counter are no longer written in language that is over our heads. Starting here and now, when children wake up sick in the middle of the night, parents won't have to read a dictionary to read the directions. And people won't need a magnifying glass to find out what's in their medicine."

FDA hopes the new "Drug Facts" labels will improve the way consumers choose and use over-the-counter medicines just as the simplified "Nutrition Facts" labels have helped consumers eat less fat and otherwise improve their eating habits.

"People have told us, and studies have confirmed, that the food labels are working," says Peter Rheinstein,

M.D., director of the medicine staff in FDA's Office of Health Affairs. "What's lacking in many OTC labels is readability, consistency—all the things the new food label has. It's not that the information isn't there already. Sometimes it's just hard to find."

Debra Bowen, M.D., who led the FDA team that wrote the regulation, sees the similarity with the standardization of the food label, and adds that using a drug correctly requires even more elaborate information about risks and benefits. So it's all the more important, Bowen says, "to provide not only complete information about the drugs, but complete information in a readable, clear and simple format."

Just the Facts

Americans buy about 5 billion over-the-counter drugs each year, according to government estimates, to treat their headaches, heartburn, coughs and colds, and other routine health problems. According to the Consumer Healthcare Products Association, a trade group that represents nonprescription drug makers, more than 600 OTC drugs contain ingredients and dosages that 20 years ago were available only by prescription.

"If you buy a drug without having all the information, you may not get all the benefit it can provide."

— Peter Rheinstein M.D.

Over-the-counter drugs are very safe as a rule, but not risk-free, Rheinstein says. "Just because something is sold over the counter," he says, "doesn't mean it's absolutely safe. Any medicine that's strong enough to help you also has the power to hurt you if you don't take it right."

Taking a medicine right can help avoid dangerous adverse reactions, it's true, but Rheinstein adds that a person who uses a medicine incorrectly can be harmed in another important, although perhaps less dangerous, way: "If you buy a drug without having all the information, you may not get all the benefit it can provide," he says. "The new rule will help people get all the benefit they're paying for."

The new label's simple language and easy-to-read format should help people compare drug products to choose the best one to treat their illness, get the drug's full benefit, and avoid unnecessary adverse reactions.

Under the rule, OTC drug labels must comply with these requirements:

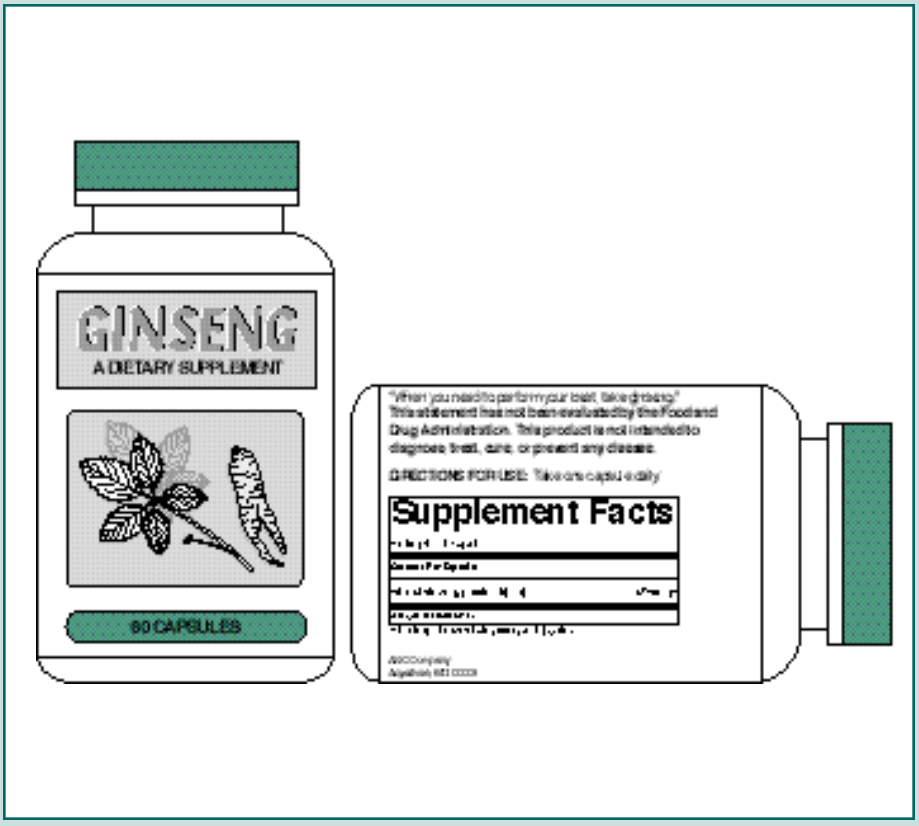
- Information must be presented in a

Supplement Facts

Like processed foods and now over-the-counter drugs, dietary supplements, too, must begin carrying standardized labels with information about their ingredients. The "Supplement Facts" panel will tell consumers the amounts of specific nutrients—vitamins A and C, calcium, iron, and sodium, for example—in vitamin and mineral products. For herbal products, the label will state the part of the plant used in the product (such as the root, stem or leaf).

The new rule went into effect March 23, but supplement makers can sell their remaining stock of products labeled before that date. FDA plans to check marketed dietary supplements to make sure they are complying with the rule.

(For more on dietary supplements, see "An FDA Guide to Dietary Supplements" at www.fda.gov/fdac/features/1998/598_guid.html.)



standardized, easy-to-follow format, usually on the package's outside container or wrapper. Under the title "Drug Facts," the product's active ingredients will be listed first, along with the purpose for each, followed by uses, warnings, directions, and inactive ingredients. Listing inactive ingredients is a new requirement that should help consumers avoid products that may cause an allergic reaction. Also, FDA recommends, but doesn't require, that manufacturers include a phone number on the label for consumers to call for more information.

- Simple language must be used to communicate critical information, such as a drug's ingredients, dose and warnings. For example, the term "uses" replaces "indications," and some other technical words like "precautions" and "contraindications" won't be used anymore, either. Studies have shown that consumers often have difficulty using the information as currently presented on OTC drugs. One study, for example, reported that 70 percent of caregivers could not measure the correct dose of medicine for their child, a problem that puts that child at risk of being overmedicated or undermedicated.
- The label must be printed in type large enough to be easily read and use other graphical methods to improve readability, such as bullets, a certain amount of spacing between lines, and thin lines separating label sections. Studies have shown that many older Americans in particular can't read the small type on some current labels. This increases their risk of taking the wrong dose of a medicine or taking a medicine that could be harmful if combined with another drug they are using.

OTC medicines must begin carrying the new labels within two to six years, depending on the drug, but FDA expects many products to have the new labels sooner.

Lightening the Load

FDA estimates that changing the labeling will cost drug companies about $58 million. Will drugs cost you more because of this rule? FDA doesn't regulate drug prices, but the agency doesn't expect prices to increase as a result of the regulation because most OTC drug labels are routinely reprinted every few years.

"We're doing what we can to make the rule nonburdensome," Rheinstein says. "Drug companies shouldn't have to throw out any labels, but in most cases can use up the old supplies first." For packages that are too small for the standardized labeling, the rule allows a modified format containing the most critical information.

Drug companies support the idea of making their labels more consumer-friendly, according to Joseph Doss of the Consumer Healthcare Products Association. "We have often said that, next to the medicine itself, the most important thing is the label," Doss says. The label is what separates OTC medicines apart from other drugs. There, the consumer has all the information needed to take the products safely and effectively.

Simplified Label Earns "No Gobbledy-Gook" Award for FDA

"The New Label—It's Clearly Better" goes the slogan for FDA's over-the-counter drug label change. For leading the effort to develop the new, "clearly better" label, the agency's Debra Bowen got a Plain Language award from Vice President Al Gore.

Gore's "No Gobbledygook" awards recognize those in the federal government who write with their readers in mind. "People should be able to understand what we write the first time they read it" is the simple reminder to government employees from Gore's National Partnership for Reinventing Government.